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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/522,727	03/10/00	MARASCO W	47577-C

HM12/0915

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EXAMINER	
ROARK, J	

ART UNIT	PAPER NUMBER
1644	6

DATE MAILED: 09/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/522,727	Marasco et al.
Examiner	**Group Art Unit**
Jessica Roark	1644

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-12* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-12* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to comply with sequence Requirements

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Sequence compliance

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is reminded that the rules apply to sequences of four or more amino acids, *including*, for example, the sequence found on page 4, line 29, and on page 14, line 28, of the specification as-filed.

Restriction election

2. The following are noted:

A) "The use" of an antibody recited in claim 6 implies a method, and that claim 6 should be grouped with claims 1-5. Further, the dependancy of claim 7 on claim 6 implies that it should be grouped with claim 6, even though the preamble reads on a product, an antibody. Thus claims 6 and 7 have been placed in Group I. However, because there is some ambiguity in the language of claims 6 and 7, claims 6 and 7 have *also* been placed in a separate group (Group II) *as they read on the antibody as a product*.

Election of *Group I* would result in an examination ONLY with respect to the *method*. Election of *Group II* would result in an examination ONLY with respect to the *antibody product*.

B) The "cell transduced by a gene encoding an antibody that binds to a target molecule" recited in claim 8 and dependant claims 9-12 is interpreted *for restriction purposes* to refer only to a target cell; that is, a cell transduced by a vector encoding an antibody which, when expressed, binds to a target molecule *within that cell*. However, claim 8 can also be interpreted to recite *any* cell transduced by a vector encoding an antibody that binds a component of the MHC. Applicant is invited to clarify the intended recitation of claim 8 for the record.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
I. Claims 1-5, and 6-7, *drawn to a method of inhibiting* an undesired immune associated reaction by transducing a cell with an antibody, classified in Class 514, subclass 885.

II. Claims 6 and 7, *drawn to an antibody* which binds to a component of the MHC complex, classified in Class 424, subclass 135.1.

III. Claims 8-11, drawn to a cell transduced by a gene encoding an antibody that binds to a component of the MHC complex, classified in Class 424, subclass 93.21.

IV. Claim 12, drawn to a kit containing a vector containing a gene encoding an antibody that binds an MHC component, classified in Class 435, subclass 810.

4. Inventions II, III, and IV are different products. An antibody used intracellularly (intrabody), a cell transduced by a gene encoding an antibody wherein the antibody acts intracellularly, and a vector containing a gene encoding an antibody that may be used as an intrabody are patentably distinct because each product differs in structure and functions at different levels.

5. Inventions (II and I), (III and I), respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the antibody can be used to detect or to purify antigens of interest as well as for the immune suppression method claimed; the transduced cell can be used a research tool to study the inhibited MHC component or as a non-stimulatory in vivo carrier of therapeutic molecules. Therefore the antibody and the transduced cell are patentably distinct.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Election

7. **Irrespective of whichever group Applicant may elect**, Applicant is further required to (1) elect a single disclosed species (that is, a ***specific target molecule***; for example, one of the single disclosed species recited in claim 2 for Group I, claim 7 for Group II, or claim 9 for Group III) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because the structures of the target molecules are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic for Group I, claim 7 is generic for Group II, and claim 8 is generic fro Group III.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 am to 4:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
September 12, 2000

Phillip Gambel
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9/14/00